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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/080,920	02/20/2002	Motasim Sirhan	020460-000230US	1180

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EXAMINER	
WEBB, SARAH K	
ART UNIT	**PAPER NUMBER**
3731	

DATE MAILED: 10/19/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/080,920	SIRHAN ET AL.	
	Examiner	Art Unit	
	Sarah K. Webb	3731	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *01 August 2006*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *See Continuation Sheet* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,2,11-18,20-23,26-28,31,32,35,45-48,69,71,73,76,79-85,97-100 and 107* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on ____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

Continuation of Disposition of Claims: Claims pending in the application are 1,2,11-18,20-23,26-28,31,32,35,45-48,69,71,73,76,79-85,97-100 and 107.

DETAILED ACTION

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

1. Claims 1,2,11-18,20-23,26-28,31,32,35,45-48,69,71,73,76,79-85,97-100, and 107 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

a. The new limitation in claim 1 that the catheter body has a balloon inflation lumen renders claim 1 and its dependent claims indefinite, because this feature is not sufficiently supported by the disclosure. The balloon inflation lumen (29) is provided by the shaft (26) – not the catheter body - which is clearly shown in cross-section in Figure 5B.

b. Claims 2 and its dependent claims remain indefinite because the claim requires the groove to extend along the sleeve passage. This feature is not adequately supported by the disclosure. As applicant has pointed out in the arguments, a groove extending along a portion of the sleeve passage would render the device inoperable.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

2. Claims 1,2,11-18,20-23,26-28,31,32,35,45-48,69,71,73,76,79-85,97-100, and 107 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

c. The new limitation in claim 1 that the catheter body has a balloon inflation lumen renders claim 1 and its dependent claims indefinite. The balloon inflation lumen (29) is actually provided by the shaft (26) – not the catheter body - which is clearly shown in cross-section in Figure 5B.

d. Claims 2 and its dependent claims remain indefinite because the claim requires the groove to extend along the sleeve passage. This feature is not adequately supported by the disclosure. As applicant has pointed out in the arguments, a groove extending along a portion of the sleeve passage would render the device inoperable.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

3. Claims 1,2,11-18,20-23,26-28,31,32,35,45-48,69,71,73,76,79-85,97-100, and 107 are rejected under 35 U.S.C. 103(a) as being unpatentable over US Patent No. 5,578,009 to Kraus et al. in view of US Patent No. 5,613,946 to McKeever.

Kraus discloses a balloon structure shaft that removably receives a guide wire through an axial groove (37) in the shaft, as shown in Figures 5-9. The shaft (54 or 71) has a passage (61 or 74) for removably receiving the guide wire (55 or 75). The shaft passage (61,74) has an axial groove (37) for removal of the elongate member (55 or 75) (see esp. Figure 5). Figures 1-2 show the balloon structure in more detail. A balloon sleeve (25) is disposed over a shaft (13) and has a passage that is slidable over a guide wire (11).

Kraus only discloses the elongate member as being a guide wire, instead of a catheter with a guide wire lumen as required by the claims. McKeever discloses a similar device in Figures 4-7 that includes a balloon catheter removably attached to another catheter. McKeever teaches that removably attaching another catheter body to a balloon catheter shaft allows for multiple tasks to be performed simultaneously (columns 1-2). Similar to Kraus, the balloon shaft communicates with a balloon while another lumen receives the second catheter body (column 1, line 67 through column 2, line 3). It would have been obvious to one of ordinary skill in the art at the time the invention was made to adjust the Kraus device to removable receive a catheter body with a guide wire lumen in place of the guide wire, as taught by McKeever, as this would provide the user with the capability of performing multiple tasks simultaneously. Further, it would have been obvious to one of ordinary skill in the art to from the axial groove of the modified Krause device so that the transverse edges of the groove are spaced from one another, as shown in Figure 7 of McKeever.

Regarding claim 23: see lines 30-40 of column 3 in Kraus.

Regarding the dimensions limitations: Kraus discloses some dimensions for the various components in column 6, line 55 through column 7. The shaft with the groove can have a length of 25 cm. Kraus states that typical catheter length is about 135 cm (column 1, line 33). The balloon length is about 3-6 cm. McKeever teaches that the diameter of a catheter is about 6-8 French (column 3, line 61) and the diameter of a guide wire lumen is about 0.035 inch (column 3, line 66). It is well known in the art for catheter bodies to taper at the distal end and have atraumatic tips. Kraus teaches that it is obvious to modify the dimensions of the device (column 6, lines 57-68).

Kraus also teaches that any materials known in the art can be used for construction of the device, including polymers and metal alloys, including nickel-titanium alloy (column 7, lines 1-10).

Regarding claims 21 and 71: It would have been obvious to one of ordinary skill in the art to form the catheter body from multiple connected members, as it has been held that constructing a formerly integral structure in various parts involves only routine skill in the art.

4. Claim 74 is rejected under 35 U.S.C. 103(a) as being unpatentable over Kraus et al. in view of McKeever, as applied to claims 1 and 2 above, and further in view of US Patent No. 5,395,335 to Jang.

The modified Kraus device fails to form the axial groove as multiple intermittent grooves, but Jang teaches that an axial groove in a catheter can be perforated as an alternative to a continuous groove (column 9, lines 35-40). It would have been obvious to one of ordinary skill in the art at the time the invention was made to form the axial groove of the modified Kraus device in a perforated configuration, as Jang

teaches that is simply a functionally equivalent way to form an axial groove in a catheter for removal of an elongate body from a lumen.

Response to Arguments

5. Applicant's arguments filed 8/1/06 have been fully considered but they are not persuasive. Applicant argues that Kraus does not disclose an axial groove extending along a portion of the shaft and the passage of the balloon structure, but this argument is moot in view of the deletion of this limitation from claim 1 and all the claims that dependent from it. Claim 2 and all of its dependent claims are still rejected under 112, since a groove in the sleeve passage is not sufficiently supported by the disclosure. Kraus is not necessarily required to disclose or suggest a slit, or groove, in the passage (41) of the balloon sleeve, because this feature is not adequately supported in applicant's disclosure. As applicant has pointed out in the arguments, a groove extending along a portion of the sleeve passage would render the device inoperable.

Conclusion

6. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and

any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sarah K. Webb whose telephone number is (571) 272-4706. The examiner can normally be reached on Mon-Fri 8-4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anhtuan T. Nguyen can be reached on (571) 272-4963. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

SKW
10/13/06

Julian W. Woo

JULIAN W. WOO
PRIMARY EXAMINER